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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,551	09/27/2001	Muthiah Manoharan	ISIS-4847	3873

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EXAMINER	
SCHULTZ, JAMES	

ART UNIT	PAPER NUMBER
1635	17

DATE MAILED: 08/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/965,551	MANOHARAN, MUTHIAH	
	Examiner	Art Unit	
	J. Douglas Schultz	1635	

--Th MAILING DATE of this communication app ars on th cov r sheet with the correspondence address --

THE REPLY FILED 23 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *28-30, and 52-69 for reasons of record.*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because: applicants' arguments regarding the instant enablement rejection are not convincing. Applicants argue that although the claims as worded are drawn to treating an organism comprising contacting said organism with the subject compound, that the claims are specifically not drawn to curing an organism, and that the term "treatment" has a lower threshold which is enabled. Applicants repeatedly object to the use of terms derived from the word "therapeutic" in previous Office actions, alleging that this imposes a higher bar than is required given the claims drawn to treatment as opposed to curing.

This is not considered convincing. As applicants are no doubt well aware, claims may be given the broadest reasonable interpretation consistent with the specification. M.P.E.P. § 2111. As a matter of record, no imposition has ever been put on applicant to demonstrate "curing" in any form, nor is one being imposed now. Despite applicants repeated attempts to steer the emphasis of their claims toward the method step of contacting an organism, the expressly claimed purpose of such contacting is for administering treatment, which is not considered to be enabled. Applicants object to any rejection based on the term "treatment", because applicants allege a lower bar exists for such langugae; however, such language does not lower any threshold in such a way as to enable the instant claims. As pointed out in previous Office actions, applicants specification demonstrates no effective treatment, other than treating cells in culture. Furthermore, applicants' argument that treatment is somehow unrelated to the therapeutic use of their compound is simply misguided. CancerWeb, a website dedicated to medical terminology, provides a definition of "treatment": "To care for medicinally or surgically; to manage in the use of remedies or appliances; as, to treat a disease, a wound, or a patient," while describing the term "therapeutic" in the following manner: "Compounds that are used to treat specific diseases or medical conditions." If applicants' intent is to establish a patentable foothold based upon possible differences in the scope of these definitions, such arguementation is not convincing, because both definitions recite treating diseases. Furthermore, as supported in previous Office actions, treating cells in a dish does not provide guidance for one of skill in the art to provide care either medicinally, or surgically, or in any other manner as explained in previous Office actions.

Applicants have also argued that the examiner has inaccurately characterized the facts of a clinical trial referenced in the previous Office action by referring to the clinical trial as a failure, and that this underscores a desire on the part of the examiner to provide clinical data to support patentability.

In response, applicants are referred to the title of the cited news article reporting on the clinical trial: "Lilly, Antisense Drug Fails in Trial". If the term "fails" is objectionable, perhaps allegations of factual inaccuracies should be directed to those who titled and distributed the article, as the examiner was simply relaying the results as reported. Applicants are also reminded that the first citation of clinical trials came from applicants; the above referenced clinical trial was cited solely to rebut applicants allegations that "other compounds that are in clinical trials...have proven that much of the prophetic criticism cited in the Office action was simply wrong" (Applicants' response filed March 25, 2003, page 13, last paragraph). To date, it is pointed out again that only one antisense drug has made it through clinical trials, and that this drug is not representative of any antisense drug for reasons of record.

Applicants contend that "while the Affinitak trial did not meet the primary endpoint for FDA approval purposes, there is no indication in the Reuters article that this antisense drug fails to exert an effect in clinical patients. However, from the cited Reuters article (3rd paragraph): "But in a statement released in London, Lilly said a Phase III clinical trial showed no statistically significant improvement in overall survival in those patients given the drug alongside conventional chemotherapy." Thus it appears that the only possible manner in which applicants statements could be considered factually correct is if we simply ignore statistical significance. This is clearly not acceptable.

Applicants finally argue that data from a subset of patients treated in the Affinitak clinical trial is "fully supportive of applicants' treating claim language". Applicants claim these data are from the Reuters article. However, no such discussion of patient subsets or results therefrom exists in said Reuters article, so it is unclear from where applicants data is gleaned. Moreover, the missing data as reproduced in applicants arguments are not significant. Accordingly, as per accepted principles of statistical probability, such data does not describe anything beyond that considered to occur by random chance. One of skill in the art would not be convinced of the enablement of claims drawn to treatment based upon results that show no difference from random chance.

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